STATE OF MICHIGAN
DEPARTMENT OF ENVIRONMENTAL QUALITY
LANSING

JENNIFER M. GRANHOLM
GOVERNOR

STEVEN E. CHESTER
DIRECTOR

November 9, 2007

VIA E-MAIL and U.S. MAIL

Mr. Ben Baker
Senior Environmental Project Leader
The Dow Chemical Company
1790 Building Washington Street
Midland, Michigan 48674

Dear Mr. Baker:

SUBJECT: Disapproval and Letter of Warning; Direct Contact Criteria Report for Midland Area Soils (DDC Report); The Dow Chemical Company (Dow), Midland, Michigan; MID 000 724 724

The Michigan Department of Environmental Quality (MDEQ), Waste and Hazardous Materials Division (WHMD), in conjunction with the Michigan Department of Community Health (MDCH), has conducted a review of the DCC Report, submitted by Dow on October 15, 2007. The purpose of this review was to evaluate Dow's compliance with their hazardous waste management facility operating license (License); Part 111, Hazardous Waste Management, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (NREPA); the corresponding requirements under Subtitle C of the federal Resource Conservation and Recovery Act of 1976, as amended (RCRA); and any administrative rules or regulations promulgated pursuant to these acts.

As a result of this review, the WHMD has determined that the DCC Report is incomplete, contains substantial inaccuracies and major deficiencies, and that Dow is in violation of the License.

Background

1. My letter to Mr. Greg Cochran of Dow, dated July 24, 2007, conveying approval of the Midland Area Soils Remedial Investigation (RI) Work Plan (RIWP) Compliance Schedule states that "The approved schedule requires the submittal of **final** documents by the specified dates" (Emphasis added).

2. My July 24, 2007, letter regarding the RIWP Compliance Schedule also states:

> These approved Compliance Schedules are components of the December 1, 2006, RIWP and, as such, become enforceable in accordance with the conditions of Dow's License. Failure to undertake the actions or responses required by this letter and enclosed approved Compliance Schedules may result in the issuance of a Notice of Violation by the MDEQ. Dow may propose, with adequate justification, revisions to these Compliance Schedules at the time the revised RIWPs are submitted

later this year. Revisions to the enclosed Compliance Schedules will require formal approval by the MDEQ.

The Implementation Schedule contained in the Midland Area Soils RIWP submitted on October 15, 2007, included the following:

> October 15, 2007 - Submit Site-Specific Direct Contact Criteria Report for Dioxins and Furans to MDEQ for Review and Approval
>
> Fall 2007 - Empanel Independent Scientific Advisory Panel [ISAP] regarding the Direct Contact Criteria Report

Dispute resolution was not requested for submittal of the DCC Report in the letter dated September 17, 2007, in which other RIWP Compliance Schedule deliverable dates were disputed. Therefore, the MDEQ expected the DCC Report to be a final document.

3. The RIWP Compliance Schedule relied on submittal of a final DCC Report by October 15, 2007, to provide sufficient time for the ISAP review (i.e., empanel, review, and produce a report), which is likely to take four to six months. This timing is critical to have adequate time to approve, or approve with modifications, the proposed direct contact criterion or set of criteria (DCC) so that the Midland data can be "unblinded" by the scheduled date of March 1, 2008. Unblinding of this data is necessary for timely implementation of the next phase of the Midland RI as required pursuant to R 299.9528.

4. Although Dow has proposed additional meetings and discussions on components of the DCC Report prior to revision and review by the ISAP, Dow has failed to resolve these issues after several meetings on these topics. The last substantive meeting on the Midland DCC was March 1, 2007. The last biweekly meeting with Dow was on June 21, 2007.

Basis for Disapproval

5. As the DCC Report is a component of the RIWP, the MDEQ hereby disapproves this document pursuant to Condition XI.B.5. of the License and provides the following examples of major deficiencies and omissions:

   A. The MDEQ found that the DCC Report, which was scheduled to be a final report with proposed DCC value(s) and sufficient to send to Toxicology Excellence for Risk Assessment (TERA) for ISAP review, to instead contains sections marked "[Intentionally left blank.]" and the following language:

      > The goal of this Report, then, is not to propose and defend one definitive site-specific DCC, but, instead, to make a good faith investigation, and present a detailed discussion, of a broad range of possible criteria, based on the most scientifically credible and best information currently available. This Report and the analysis herein can serve as the basis for future discussions between Dow and the

> MDEQ, before particular issues and points related to dioxin risk assessment relevant to the development of site specific criteria are posed to an Independent Science Advisory Panel ("ISAP").

Also,

> This Report attempts to be as comprehensive as possible given the limited time provided. However, Dow may submit supplements to this Report as its assessment continues. Further, for the sake of brevity, some details and analysis upon which the calculations have been based have been left out of this Report. Dow is willing and prepared to provide additional detail and discuss the additional detail and analysis as would be useful to MDEQ. In this regard, Dow invites questions from the MDEQ and looks forward to meetings with the MDEQ to discuss the calculations in more detail and to prepare the charge questions for the ISAP.

B. Omission of Final Proposed Site-Specific DCC

The DCC Report provides a range of values, but does not provide a proposed site-specific DCC (e.g., residential, commercial, and industrial) for Midland Area Soils.

C. Omissions – "[Intentionally left blank.]"

1) Section 3.1.4, page 31
2) Section 3.1.7, page 37
3) Section 3.2.1.2.1, page 57
4) Section 5, page 97

D. Detailed justifications were not provided for each exposure assumption proposed for change from those in R 299.5720 for calculation of a site-specific DCC. Detailed justifications must be provided and include a demonstration of how the change is protective of the public health, safety, and welfare and the environment. This information is required for the MDEQ to review and approve the DCC Report pursuant to Section 20118(1) and (2) of Part 201, Environmental Remediation, of the NREPA, and R 299.5705(1) of the Part 201 Rules.

E. Detailed justifications were not provided for each toxicity assumption proposed for calculation of site-specific DCC. Detailed justifications must be provided and include a demonstration of how the toxicity assumptions are protective of the public health, safety, and welfare and the environment. This information is required for the MDEQ to review and approve the DCC Report pursuant to Section 20118(1) and (2) and R 299.5705(1).

F. Dow indicated in the DCC Report that "some details and analysis upon which the calculations have been based have been left out of this Report."

6. Additional comments are provided in the enclosed Attachment 1 to assist Dow in revising the DCC Report. These comments illustrate further examples of areas that could be better clarified, corrected, or improved in the DCC Report, and include examples of the following:

   A. Selective citation of applicable regulations and guidance.

   B. An incomplete basis, inaccuracies, or inconsistencies in the basis for several of the proposed assumptions.

   C. Selective use of "best available information."

   D. Incomplete evaluation of uncertainty and variability.

7. Condition XI.B.5. of the Dow License states:

   > The licensee shall submit a written RI Work Plan to the Chief of the Waste and Hazardous Materials Division in accordance with the SOW [Scope of Work] approved pursuant to Condition XI.B.4. of this license. The Chief of the Waste and Hazardous Materials Division will approve, modify and approve, or disapprove the RI Work Plan, or provide a written Notice of Deficiency on the RI Work Plan. The licensee shall modify the RI Work Plan in accordance with or based on the resolution of the Notice of Deficiency and submit a new RI Work Plan or revisions to the RI Work Plan to the Chief of the Waste and Hazardous Materials Division for approval within 60 days after receipt of the Notice of Deficiency. Upon approval by the Chief of the Waste and Hazardous Materials Division, the RI Work Plan becomes an enforceable condition of this license. The licensee shall implement the approved RI Work Plan in accordance with the schedule in the RI Work Plan.

Violations and Required Responses

8. Dow's failure to submit an approvable DCC Report in accordance with the MDEQ approved schedule is a violation of Condition XI.B.5. of the Dow License. Dow shall, by the dates indicated below, take the following actions:

   A. Dow shall provide **by November 26, 2007,** a complete, revised DCC Report that proposes a specific DCC to the MDEQ for review and approval and for review by the ISAP. The revised DCC Report shall address the deficiencies and omissions noted above and the comments contained in Attachment 1.

   B. To cover the estimated costs for TERA to conduct the ISAP review as documented in the enclosed Attachment 2, Proposal for Peer Review of the Direct Contact Criteria Report for Midland Soils, dated November 5, 2007, Dow must add an additional $200,000 to the escrow account **by December 3, 2007**.

If a complete document is not provided by Dow within the time frame specified above, the current submittal and associated documentation (e.g., Sensitivity Analysis, Bioavailability

Proposal) will be sent to TERA for ISAP review **by December 10, 2007**. This is necessary to prevent further delay in the implementation of the next phase of the RI for the Midland Area Soils Area of Concern. The MDEQ will complete the review of the DCC Report in accordance with the provisions of Condition XI.B.5. of the License after receiving the input from the ISAP.

This Letter of Warning does not preclude, nor limit, the MDEQ's ability to initiate any other enforcement action under state or federal law, as deemed appropriate.

If you have any questions regarding this matter, please contact Ms. DeLores Montgomery, Acting Chief, Hazardous Waste Section, WHMD, at 517-373-7973 or by e-mail at montgomd@michigan.gov, or you may contact me.

Sincerely,

George W. Bruchmann, Chief
Waste and Hazardous Materials Division
517-373-9523

Enclosures
cc: Ms. DeLores Montgomery, MDEQ
Ms. Cheryl Howe, MDEQ
Dr. Deb MacKenzie-Taylor, MDEQ
Mr. Allan Taylor, MDEQ
Mr. Gary Tuma, MDEQ
cc/enc: Mr. Greg Cochran, Dow
Mr. David Gustafson, Dow
Mr. Peter Wright, Dow
Mr. Greg Rudloff, U.S. Environmental Protection Agency, Region 5
Dr. Mark Johnson, Agency for Toxic Substances and Disease Registry, Region 5
Mr. Robert P. Reichel, Michigan Department of Attorney General
Ms. Kathleen L. Cavanaugh, Michigan Department of Attorney General
Dr. Linda Dykema, MDCH
Mr. Jim Sygo, Deputy Director, MDEQ

ATTACHMENT 1

Additional Comments for the November 7, 2007, Disapproval and Letter of Warning; Direct Contact Criteria Report Midland Area Soils (DCC Report); The Dow Chemical Company (Dow), Midland, Michigan; MID 000 724 724

The following additional comments are provided to assist Dow in revising the DCC Report. These comments illustrate further examples of areas that could be better clarified, corrected, or improved in the DCC Report.

Section 2.3.3 University of Michigan Dioxin Exposure Study [UMDES]
This section attempts to make comparisons between estimates of dioxin exposure derived from a soil intake algorithm and estimates of dioxin exposure derived from measurements of blood serum dioxin levels. There are a number of reasons why these comparisons are either flawed or represent inappropriate ways for making quantitative intake/dose comparisons.

(1) Chemical intake algorithms such as those shown in Section 2.1.3 represent an estimate of an "administered dose" to a subject (i.e., test animal or human). The administered dose is the dose available at the exchange boundary for absorption. This administered dose value is combined with a toxicity factor (e.g., Cancer Slope Factor, Reference Dose [RfD]) that is also based on a metric corresponding to the administered dose in toxicological studies of a chemical in animals or the estimated administered dose from epidemiological studies of human health effects. The intake rate and the toxicity factor are combined to make cancer risk and noncancer hazard estimates corresponding to the administered dose rate. In some cases, the intake algorithm may be modified to account for the bioavailability of the chemical from the soil type to which the animal or human could be exposed. In that case, the estimated intake could correspond to an "absorbed dose" or "internalized dose" in the sense that it corresponds to the dose that goes beyond the exchange boundary. It is not clear that this absorbed dose estimate can be regarded as the actual dose distributed to a specific body compartment or organ/tissue compartment. Therefore, the suggestion that a chemical dose estimate from an intake algorithm (even if adjusted for bioavailability) should be directly compared to the actual dose reaching a specific body compartment (e.g., blood serum lipids, liver cells) could be uncertain and would not be appropriate without significant information about the distribution, excretion, and binding of the chemical after absorption.

(2) This section states that some residents included in the various study population groups of the UMDES (August 2006) resided on property at which at least one soil sample was found to have a dioxin toxic equivalent (TEQ) concentration of 1000 parts per trillion (ppt) or nanograms per kilogram (ng/kg). The authors of the UMDES presented results indicating that for study subjects who resided on such property for at least five years: (1) the measured blood serum dioxin TEQ concentration was positively correlated with dioxin soil TEQ concentration and (2) the observed contribution of soil dioxin to blood serum dioxin TEQ was 0.7 ppt. However, the UMDES authors **do not** state or imply that a dioxin soil concentration of 1000 ppt TEQ should be regarded as the long-term average concentration (i.e., exposure point) for persons who reside on such properties. In fact the UMDES data indicate that the finding of soil samples at 1000 ppt TEQ or above was a rather infrequent occurrence with only 4 percent of all properties having at least one soil sample at 1000 ppt or above. In the UMDES area showing the highest soil concentrations (Midland Plume), the median soil TEQ was 59 ppt (house perimeter samples), and for all UMDES areas the 95th percentile TEQ concentration was 67 ppt (Garabrant 2007). Consequently, a reasonably

conservative estimate of the long-term average exposure concentration for persons living on a property with one sample of 1000 ppt TEQ could be 100 ppt. This means that persons living on a property with a 1000 ppt soil sample could actually have a long-term TEQ concentration of 100 ppt which causes the observed blood serum TEQ increment of 0.7 ppt. If a TEQ of 100 ppt is used as the soil TEQ input for the example calculations in this section (page 23), the calculated blood serum increment would be about 1.0 ppt (ng/kg lipid) when the MDEQ default parameters are used to calculate an absorbed average daily dose of 0.08 picograms/kilogram-day. The 1.0 ppt TEQ estimate using default parameters compares favorably with the measured increment of 0.7 ppt TEQ reported in the UMDES. Consequently, it appears that the use of the Part 201, Environmental remediation, of the Natural Resources and Environment Protection Act, 1994 PA 451, as amended (NREPA), and its administrative rules intake algorithm combined with MDEQ default exposure parameters and a realistic exposure point concentration would not result in an excessive (20-fold) overestimate of the actual blood serum TEQ increment.

(3) This section does not consider that the increment provided by the UMDES researchers is an average value for the approximately thirty subjects with maximum soil sample concentrations on their property over 1,000 ppt. The exposure assumptions used for risk assessment by the MDEQ, and according to U.S. Environmental Protection Agency (U.S. EPA) guidance, represent a reasonable maximum exposure (RME) or upper percentile. It is not expected that the average and a RME would be the same. It is not surprising that the RME was almost 20 times the average exposure. As demonstrated by the criterion values provided in Dow's Calculation Appendix deterministic values with only the exposure assumptions changed. The differences between these two values (90 ppt and 770 ppt) intended to represent an RME is 8.5 times, so the difference between an average exposure and RME would be expected to be much greater.

This section must be revised to incorporate the concerns and alternatives described above. Also, the origin for the one-compartment model for estimating serum lipid TEQ increment should be provided.

Section 3.1 Exposure Variables

The DCC Report requires additional information to clearly and transparently provide the approach used and basis for the input parameters proposed for a site-specific direct contact criterion or set of criteria (DCC).

The additional information needed includes the basis for all exposure parameters that have been changed from the values in R 299.5720 of the Part 201 Rules. This information must include why the changes better represent site-specific exposures for both the deterministic and probabilistic inputs. For probabilistic inputs, the underlying data, any manipulations of the data and basis for the shape of the distribution must be clearly described and justified. The DCC Report must clearly justify deviation from values in the Part 201 Rules and/or U.S. EPA guidance.

Some specific examples are provided below.

Section 3.1.1 Ingestion Exposure Frequency.
The section does not consider the values provided in the following U.S. EPA guidance:

- U.S. EPA Risk Assessment Guidance for Superfund (RAGS) Part B (1991)
- U.S. EPA Soil Screening Guidance (1996)

The soil ingestion exposure frequency is linked to the soil ingestion rate. The soil ingestion rate data sets do not differentiate from days/time spent outdoors with time spent indoors for the short periods the soil ingestion data was collected. Unlike the dermal adherence data, which is outdoor activity specific, the soil ingestion data cannot be linked exclusively to time spent outdoors. These data sets are average daily exposure representing times with both indoor and outdoor activities.

Sections 3.1.7 Soil Ingestion Rate (Child) IR_{child}
Since this section is using a placeholder value, this placeholder value should be the current MDEQ generic residential soil ingestion rate for children of 200 mg/kg until the MDEQ is provided the opportunity to evaluate a proposed value when developed by Drs. E.J. Calabrese and E.J. Stanek.

Instead, Dow has proposed to use as a placeholder, a child soil ingestion rate that is based on a study with the lowest soil ingestion rates in the published literature. This study was conducted in Anaconda, Montana, in an area known to be a Superfund site. The study authors raise concerns that about the observed lower soil ingestion rates in this study population as follows:

"Lower soil ingestion by children at Anaconda is plausible since families were aware that they lived on an EPA Superfund site, and such knowledge may have resulted in reduced exposure or altered behavior. This explanation remains hypothetical and requires further investigation." (Calabrese et al., 1997).

The study authors also point out that there is significant negative error with this approach and dataset. Therefore, the estimates provided by this method are lower than the true value (Calabrese et al., 1997). The MDEQ notes that this is a prevalent problem with the soil ingestion data. Dow has chosen this selective placeholder when more appropriate "best available information" is available from the Part 201 Rules and/or U.S. EPA guidance.

Section 3.1.8 Soil Ingestion Rate (Adult) IR_{adult}
The use of a value for the adult ingestion rate that is half of the child rate because that is the ratio for the MDEQ values is not a tenable approach. The MDEQ did not simply divide the child ingestion rate by two. The MDEQ uses a value for this parameter that is recommended by the U.S. EPA and is based on data from a limited study of soil ingestion in adult volunteers.

Section 3.1.9 Ingestion Absorption Efficiency AE_i
This section describes studies and conclusions for making a site-specific adjustment in the quantitative term that represents the oral absorption efficiency for dioxin in soil. The MDEQ currently recognizes a default oral absorption efficiency (i.e., relative bioavailability adjustment [RBA]) value of 50 percent for dioxins in soil based on published literature studies of dioxin absorption from ingested soils. The current situation concerns whether further downward

adjustment of the 50 percent value is reasonable when Midland Area soils are the focus of the exposure study.

This section provides a limited summary of the methodology and conclusions from three other reports that are found in the appendices to the DCC Report. The methodologies and results of the Midland Area soils selection studies and the animal bioavailability studies are not described in this section. Consequently, readers and reviewers of this section will gain only a limited understanding of the studies, data, and comparisons relied upon for the conclusions about the site-specific deterministic value for AE_i proposed in this section. To increase transparency for the new reader/reviewer, at a minimum, this section must be revised to address the following concerns and questions.

(1) The AE_i term is defined as the fraction of intake that passes the exchange boundary and goes into the bloodstream. For the bioavailability studies in animals, only the final RBA result is listed on page 73, Table 3-3. The report needs to describe the metric(s) that were used to represent the oral absorption efficiency of dioxin in test animals and explain why the selected metric is the appropriate one to use for representing the oral absorption efficiency.

(2) This section needs to summarize the background study of Midland Area soils and describe the investigations and criteria that were used to define a "Midland Area" soil type. The Pilot Bioavailability Study (February 2005) indicates that a single soil type from one location was used to represent Midland Area soils in all animal bioavailability studies. The DCC Report must provide adequate justification for the use of a single soil type from one location for making quantitative decisions for adjusting the oral absorption efficiency.

(3) The results of the animal bioavailability studies are shown on page 73, Table 3-3 as TEQ-weighted relative bioavailability fractions. The results imply an RBA range of 23-29 percent for swine and a value of 37 percent for rats. However, only the results for the swine study were selected for assigning a deterministic and probabilistic value for RBA. Please explain why the methodologies and results of the bioavailability studies are sufficient to justify the apparent conclusion that a significant species difference exists for the RBA of dioxins in Midland Area soils and that the RBA results in swine should be relied upon at the exclusion of the rat RBA results. Concerns about reaching a conclusion on a species difference include the following:

   (a) Methods for administering the dioxin contaminated soil were different in each species;
   (b) Body weights and growth rates of the two species differed significantly during the feeding period, with volume of distribution in the swine more than doubling in the feeding period;
   (c) RBA results were apparently based on congener retention in the liver tissue of rats versus the adipose tissue in swine;
   (d) Because lipid distribution volumes and body-mass index (BMI) may be significantly different for the two species, a BMI adjustment for the lipid retention data may be needed before the RBA results of the two species are directly compared; and
   (e) The authors of the Pilot Bioavailability Study noted the differences in physiology between the two species and the differences in soil feeding methods and congener distribution patterns across body tissues. One of their observations was: "However, there is a lack of comparative studies among swine, rats, and humans for assessing the bioavailability of lipophilic compounds, so **there is no clear reason to prefer swine over rats as a**

model for human bioavailability of PCDD/Fs from soil." (Emphasis added) (Pilot Bioavailability Study, February 2005: "Comparative Evaluation of Rat and Swine Models," page 17)

Section 3.2 Toxicity Variables

The toxicity values also require additional information to clearly describe and justify the choices made for the specific endpoints, the datasets, the extrapolations and uncertainty factors used in developing the proposed site-specific DCC. It appears that there is selective use of the Part 201 Rules and U.S. EPA guidance in developing these input parameters.

The revised DCC Report must continue to include the DCCs based on a the linear cancer potency estimate and evaluate other potential effects to adequately determine the most sensitive effect as required by Section 20120a(4) of Part 201 of the NREPA.

Section 3.2.1 Cancer Slope Factor ("CSF")

This section selectively cites part of R 299.5738(5) of the Part 201 Rules and states, "calculations in this Report use the up-to-date species scaling factor of ¾ as required by the Part 201 Rules." This citation excludes the applicable portion for dioxin cancer assessment as follows: ". . . However, if adequate pharmacokinetic and metabolism studies are available, then these data may be factored into the adjustment for species differences on a case-by-case basis." It is not clear from reviewing the report whether the species scaling factor was used or pharmacokinetic modeling was used. The use of pharmacokinetic and metabolism studies in the form of a body burden approach has been recommended by the U.S. EPA Dioxin Reassessment peer review panels (including the latest peer review by the National Academy of Sciences [NAS]) and has been used by the World Health Organization/Food and Agriculture Organization of the United Nations, Joint Expert Committee on Food Additives (WHO/FAO, 2001); The European Commission, Health and Consumer Protection Directorate-General, Scientific Committee on Food (EC, 2001); and the United Kingdom, Environmental Agency (UK, 2003) as the best available science. The DCC Report must be revised to clearly demonstrate the body burden approach or an equivalent pharmacokinetic modeling approach is included.

Page 50, first paragraph: This paragraph recognizes that chemical risk assessment requires the extrapolation from doses administered in experimental studies to possible lower doses encountered in actual environmental exposure. The DCC Report inaccurately indicates that application of a linear dose-response extrapolation and the use of the MDEQ published slope factor would result in the prediction that "virtually every person on earth would develop cancer" from exposure to background levels of dioxin (footnote 28). This paragraph must be revised to state that application of a linear dose-response model means that some finite cancer risk is associated with low-dose exposure; and footnote 28 should be deleted.

Page 56, last paragraph: It is possible that Indole-3-carbinol (I3C) has aryl hydrocarbon receptor (AHR) binding activity and tumor promoting activity and may demonstrate some tumor growth inhibiting properties in controlled clinic situations. However the DCC Report should refrain from drawing causal and/or quantitative parallels between AHR binding/activation by I3C and 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) and the biological outcomes of AHR activation by the two chemicals. For example, the biological outcomes resulting from the cancer promotion caused by TCDD may well be irreversible and not be a "*phenomenon that can be managed*" (emphasis added) as stated in this paragraph.

Section 3.2.1.2.2 Dose-Response

The first two paragraphs present contradictory explanations for potential steps in the biological effect cascade for TCDD. For example, the first paragraph states that evidence supports the non-linearity in dose-response for each key event necessary for TCDD to exhibit its cancer response. But the second paragraph states that receptor binding occupancy is recognized as being linear at low doses. The DCC Report must clarify the basis for concluding that TCDD dosing and biological responses follow a non-linear mechanism.

Section 3.2.1.2.3 Weight of Evidence

In regard to the bullet points on page 62:

Bullet 1: There may be a low level of activated AHR that serves some normal biological or homeostatic mechanism, but this normal AHR activity does not presumably require TCDD to be present. Consequently, it is not clear why activation of AHR by a ligand that results in different and abnormal biological responses cannot possibly follow a linear mechanism.

Bullet 2: The DCC Report does not provide a description of the actual evidence for concluding that humans are less sensitive to the cancer initiating and promoting effects of TCDD with achievement of equal internal body burden or tissue burden levels in both organisms and quantification of lifetime-of-exposure cancer outcomes.

Bullet 4: There is not scientific agreement or consensus with Dow's the conclusion that epidemiological studies show no increased risk of cancer from TCDD/dioxin exposure, especially when total cancer incidence is included in the analysis as evidenced by the conclusions of the International Agency for Research on Cancer and the U.S. Department of Health and Human Services, Report on Carcinogens, 11th edition, 2005.

Bullet 5: It is difficult to understand why this information on levels of dioxin in food has a bearing on the TCDD mechanism of action and the conclusion for adopting a threshold approach to cancer risk.

Section 3.2.1.2.4 Physiological Role of the AHR

Page 65, last sentence of paragraph continued from page 64: Clear quantitative evidence must be provided to support the concept that humans may be less sensitive than rats to cancer induction by TCDD and to support the conclusion that at least a 10 times factor should be applied.

Section 3.2.1.3 Methods

Page 70: It appears that the DCC Report and the Maruyama and Aoki (2006) study utilized the incidence of liver adenomas for dose-response modeling. However, an expedited review of the National Toxicology Program (NTP) study (2005) results indicates that the NTP concluded that additional neoplasms of the liver were considered to be treatment related and should reasonably be factored into the dose-response analysis. In particular, cholangiocarcinomas of the liver were regarded as treatment related neoplastic effects. The data were reported as:

Doses by gavage:

0, 3, 10, 22, 46, or 100 ng/kg, and 100 ng/kg (stop-exposure)

Liver neoplastic tumor incidence per corresponding dose group:

hepatocellular adenoma (0/53, 0/54, 0/53, 0/53, 1/53, 13/53, 2/50);
cholangiocarcinoma (0/53, 0/54, 0/53, 1/53, 4/53, 25/53, 2/50)

The above analysis utilizing additional information from the NTP study indicates that a significantly higher fraction (proportion) of study animals exhibited neoplastic lesions than were utilized for quantitative dose-response analysis in the Maruyama and Aoki study and the DCC Report. (If tumor data on each animal are reported in the NTP study, then the quantitative dose-response modeling could also utilize that data as a way to increase the relative sensitivity of the study results.)

The DCC Report must be revised to address the following Part 201 Rule and U.S. EPA guidance:

> R 299.5738(6): Additional adjustments shall be made to the data as appropriate. For some cancer data sets, it may be appropriate to combine incidences of multiple tumor types or combine benign and malignant tumors of the same histogenic origin. All doses shall be adjusted to give an average daily dose over the study duration. Adjustments shall be made to the tumor incidence for early mortality. Animals dying before the appearance of the first tumor within their dose group shall be removed from the data set. Before quantification of the dose response, a goodness-of-fit evaluation of the data shall be conducted.
>
> U.S. EPA guidance: Because an agent may induce multiple tumor types, the dose-response assessment includes an analysis of all tumor types, followed by an overall synthesis that includes a characterization of the risk estimates across tumor types, the strength of the mode of action information of each tumor type, and the anticipated relevance of each tumor type to humans, including susceptible populations and lifestages (e.g., childhood)." (U.S. EPA, 2005)

Section 3.2.1.4.1 Identification of the Critical Effect/Data Set

On page 71, first paragraph, the DCC Report states that published epidemiology study data on the cancer potency of TCDD can be discounted because some evidence exists (Aylward et al., 2005) that elimination of TCDD in the human may affect the calculation of internal TCDD retention/dose levels. The methodology details and conclusions and of the Aylward et al., 2005 study are not transparent as presented in the DCC Report. This is not a sufficient rationale for dismissing the use of epidemiology study data as part of a meaningful dose-response analysis.

The DCC Report must be revised to address the following Part 201 Rule:

> R 299.5738(2): . . . If acceptable human epidemiologic data are available for a hazardous substance, then those data shall be used to derive the risk-associated dose. . . .

Section 3.2.1.4.5 Selection of the Point of Departure
On page 73, Table 3-3, human equivalent doses were apparently derived from the internal liver doses measured or calculated in animals used in the NTP study (footnote 1). The DCC Report must explain how these values were calculated/derived from the unit risk values presented in the Maruyama and Aoki study. Specifically the DCC Report needs to be revised to document how the human equivalent doses were derived (i.e., using the body burden approach or acceptable equivalent and not body weight to ¾ power the scaling factor for animal-to-human dose-response).

Section 3.2.3.1 Derivation of a Reference Dose for Non-Cancer Risks of TCDD and
Section 3.2.3.1.2 Identification of the Critical Effect/Data Set
The DCC Report selects a series of studies conducted by Bell et al., (2007a, b, c) as the basis for a noncancer RfD. The discussion of the subchronic exposure study, which consisted of dosing female rats with 0, 2.4, 8, and 46 ng/kg of body weight per day for 12 weeks prior to mating and through parturition, is provided on page 84 of the DCC Report. The discussion correctly identifies delay in balano-preputial separation (BPS), an indication of male puberty in rats, as the most sensitive effect observed in the study. However, the DCC Report does not rely on this effect as the basis for calculation of the RfD.

On page 84, second full paragraph, the DCC Report states, ". . . the effects of TCDD on BPS noted in these two studies appear to be related to the effects of TCDD on body weight." This statement is not consistent with the conclusions reached by Bell et al., (2007a, b ,c).

In Bell et al., 2007c the authors present a plot of relative decrease in body weight on postnatal day (PND) 4 versus delay in BPS (r^2 ~0.9) and postulate that the two effects are due to lactational transfer of comparatively large amounts of TCDD. The authors do not suggest that delay in BPS is a ***result*** of decreased body weight on PND 4 or during any subsequent period in the study. In fact in Bell et al., (2007b), the authors state that ". . . the body weight at PND 21 or 42 does not affect the delay in BPS." Rather the authors use these data to elucidate the role of lactational transfer in the effects of TCDD noted in the study.

On page 84, Table 3-5, the second column is entitled "Peak Maternal Body Burden during Gestation (ng/kg)" yet the values provided are identified in the row title as "Subchronic (PND 44)." It is not clear how maternal body burdens on PND 44 could be assessed when Bell et al., (2007b) reports that parental generation females were killed on PND 21.

Section 3.2.3.1.3 Identification of a Dose Measure
It is not clear what body burden levels were actually used in the benchmark dose (BMD) analysis since the values in Table 3-5 do not correspond to any of the values presented in Table 5 of Bell et al., (2007c). Fetal body burdens on gestational day 21 are reported in Table 4 of Bell et al., (2007c) and could be used to support a dose-response evaluation for neonatal exposure.

Section 3.2.3.1.6 Selection of Response Level(s) (Point of Departure)
Aside from the question of appropriate response measure for the BMD analysis, no justification is provided for the selection of one standard deviation as sufficient to produce the effect on BPS. The acronyms used in this section are not consistent with those used in Figure 3-4 on page 86.

On page 86, Figure 3-4 indicates a BMD of 99.4 ng/kg and a 95 percent lower confidence limit on the BMD (BMDL) of 67.0 ng/kg. The BMD of 99.4 ng/kg is higher than the maternal body burden value reported in Table 3-5 for the high-dose females. Bell et al., (2007c) reports a peak maternal body burden in the high-dose group as 111 ng/kg at gestation day 21. In the previous report, the authors report a frank effect of fetal and postnatal pup mortality resulting in a roughly 26 percent reduction in pup numbers in the high-dose group as compared to controls. Bell et al., cite these data as confirmation of "the extraordinary potency of TCDD as a developmental toxicant." Dow's proposal to use the body burden level of 99.4 ng/kg, converted to an equivalent human dose, as the basis for noncancer reference dose is therefore neither supported nor acceptable.

Similarly, the BMDL of 67.0 ng/kg, which falls between the body burdens reported for the mid- and high-dose groups, is not acceptable. Bell et al., reports a statistically significant delay in BPS in the low-dose group at a maternal body burden on gestation day 21 of 13.4 ng/kg. The proposed BMDL is five times higher than the maternal body burden identified as the lowest observed adverse effect level in this study.

The formula presented on page 86 for converting a BMD or BMDL derived from the Bell et al., (2007a, b, c)studies includes a factor to account for bioavailability from soil. Leaving aside the issue of the appropriate numerical value for this factor, this adjustment may only be used once in calculating the soil DCC (SDCC). Bioavailability may be accounted for here when converting an animal dose to an equivalent human dose, or it may be used in the algorithm used to calculate the DCC; not in both.

Section 3.2.3.1.7 Uncertainty Factors

No specific comments are provided here since the choice of uncertainty factor values are dependent upon both the study and critical effect chosen as the basis for the development of an RfD. However, the statement made on page 88, bullet 2 that, ". . . reduced body weight was not accompanied by other adverse effects in rats and . . . reduction in body weight is considered to be a minimally adverse [effect]," is not supported by the results reported in Bell et al. **All** dosed groups exhibited a statistically significant delay in BPS **and** the high-dose group, which exhibited the greatest reduction in body weight, also exhibited a 26 percent reduction in pup survival.

Section 3.2.4 Relative Source Contribution [RSC]

This section makes arguments against the MDEQ identification of a 20 percent RSC (i.e., 0.2) for use when developing a SDCC for dioxin based on a noncancer endpoint. The RSC factor represents the proportion of the total daily exposure to a chemical that is attributed to or allocated to a specific medium; in this case the soil.

Dow contends that the MDEQ does not have the legal authority to depart from the soil default RSC factor of 1.0. Section 20120a(4) of Part 201 of the NREPA states, "For the noncarcinogenic effects of a hazardous substance present in soils, the intake shall be assumed to be 100% of the protective level, unless compound and site-specific data are available to demonstrate that a different source contribution is appropriate." The MDEQ rationale for a 20 percent RSC factor for dioxin is provided in the documents to which Dow referred in the DCC Report, specifically the MDEQ Interoffice Communication, Relative Source Contribution Factor for Part 201 of the NREPA, Soil Direct Contact Criteria (February 10, 2000). In summary, it is well-documented that the average person receives a significant portion of their exposure to

dioxin from food. Although dioxin levels in food products are not specifically available for the Midland area, food product data from other areas in the U.S. and from national surveys are available. Food supplies in the U.S. may be shipped long distances and most major brands are marketed nationally. Many nationally available food products are commonly consumed on a daily basis by the average U.S. citizen. As such, it is reasonable to conclude that national food product data is applicable to the Midland area such that the data can be considered "site-specific". Please note the UMDES reported that diet is a major contributor to blood dioxin levels for their study population including people living in the Midland area. The RSC factor in the SDCC equation accounts for this exposure by reducing the concentration in, or exposure from, soil such that it allows for the additional and significant exposure received from food. Ignoring this information would result in the development of a site-specific SDCC that would not be protective of public health. If Dow believes that the people of Midland receive a significantly different food supply and different levels of dioxin in their food, Dow should provide that supporting documentation. The information provided in the DCC Report did not support increasing the RSC from 0.2 to 1.0 for dioxin.

Dow's argument is ill-founded in that the use of an RSC factor lower than 1.0 contradicts the Part 201 Rules by making a regulated party liable for contamination they did not cause (i.e., the contamination in the food supply). Consideration of other exposures to a contaminant of concern in establishing a cleanup criterion is a reasonable, health-protective, and common practice. Protection of public health requires that these other exposures be incorporated into the cleanup criteria particularly for dioxin and other contaminants that are commonly present at significant levels in other media and are persistent, bioaccumulative, and toxic.

The MDEQ's review also indicates that Dow inappropriately compared dioxin to lead in terms of their relative source contributions. During the development of the Part 201 of the NREPA criteria for lead, the decision was made to assume that exposure to lead-based paint was minimal, i.e., a concentration of 200 ppm of lead in house dust was assumed; this concentration is associated with lead-based paint in good condition. The U.S. EPA, Integrated Exposure Uptake Biokinetic Model (Model) quantifies exposure to lead in food, house dust, outdoor soil, drinking water, diet, and air. The Model was used in developing the Part 201 of the NREPA drinking water and SDCC for lead; lead is the only hazardous substance for which this model is used to develop cleanup criteria. Lead is generally present at measurable levels as a natural constituent of soil whereas dioxin is not. The decision was made to assume minimal exposure to lead from paint in development of the Part 201 of the NREPA lead criteria for the following reasons: assuming significant exposure to lead-based paint in poor condition resulted in risk-based criteria lower than naturally occurring soil background levels; the Michigan Department of Community Health had a program in place to address exposures to deteriorating lead-based paint; and a small proportion of Michigan's population is exposed to deteriorating lead-based paint.

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ATTACHMENT 2
November 7, 2007, Disapproval and Letter of Warning;
Direct Contact Criteria Report, Midland Area Soils, Midland, Michigan;
The Dow Chemical Company (Dow); MID 000 724 724

Proposal for Peer Review of the Direct Contact Criteria Report for Midland Soils

Submitted by:

Toxicology Excellence for Risk Assessment
(*TERA*)

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November 5, 2007

I. Subject

Toxicology Excellence for Risk Assessment (*TERA*) is pleased to submit the following proposal to provide a 3 day peer review of the Direct Contact Criteria Report for Midland Soils. The document is being developed by the Michigan Department of Environmental Quality (MDEQ) Chemical Company (referred to as "the sponsor"). *TERA* is an independent non-profit organization with a mission to protect public health through the best use of toxicity and exposure information in the development of human health risk assessments. As a non-profit organization, *TERA* provides toxicology, risk assessment, and peer review and peer review services to both public and private sponsors. *TERA* proposes to organize and conduct an expert peer review on the subject document for MDEQ.

II. Scope of Work

TERA will organize and conduct an independent scientific peer review of the Direct Contact Criteria Report for Midland Soils. The objective of the peer review is to obtain an independent review of the calculation of a site-specific residential soil direct contact criterion (DCC) for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD). We have developed our peer review and consultation program drawing upon the procedures and practices used by a number of organizations for expert scientific panels and our own extensive experience organizing and conducting peer reviews and reviews. *TERA* would assign a team of staff scientists to this project to serve as the organizers and coordinators of the review, as well as two senior scientists to serve as the panel facilitator and co-facilitator. The *TERA* process for organizing and conducting the peer reviews and reviews involves a number of steps beginning several months prior to the meeting. These include:

- Screening the document to insure that it is ready for review, to identify critical scientific issues and questions for the charge, and to identify needed expertise for the panel;
- Identification of appropriate expert candidates and selection of panel members, including the consideration and management of conflict of interest and bias;
- Meeting arrangements and support;
- Conducting the peer review and preparing a meeting report summarizing discussions, conclusions, and recommendations; and
- Distribution of the results to the public.

The following describes how we will organize and conduct the peer review. Our website provides many of our policies and procedures for organizing and conducting these types of efforts (see www.tera.org/peer).

Task 1: Pre-review (screening) of Draft Document.

TERA will conduct a preliminary screening of the document to evaluate whether the work product is "ready" for the review meeting. Senior *TERA* scientists will read the document to evaluate whether sufficient data are provided for the reader to follow the lines of reasoning and reach conclusions, whether there is obvious information missing, and whether the text is clear and readable.

The *TERA* team will discuss with the sponsor the goals and objectives for the expert review, the scope and content of the work product to be reviewed, the important scientific issues and areas of potential controversy, the preferred location and date(s) for the meeting, and agree on a timeline for the project.

Task 2: Development of the Charge.

During the *TERA* preliminary review of the draft document and in discussions with the sponsor, *TERA* will identify the key scientific issues involved to focus the panel discussions and include in a charge for the panel. *TERA* will work with the sponsor to develop the charge, a list of issues and questions to focus the panel's discussions and comments. *TERA* will be responsible for the final wording of the charge questions to insure they are objective and comprehensive.

Task 3: Identification of Experts

During the *TERA* preliminary review of the draft document, *TERA* will also identify or confirm the types of scientific expertise needed for the peer review. *TERA* staff will identify appropriate and qualified experts from the *TERA* database of reviewers, as well as Internet and literature searches and personal contacts and referrals. It is anticipated that there will be two panels, with some overlapping of panel members. The panel for the exposure section will include experts in exposure assessment, bioavailability, and risk assessment. The panel for the human health toxicity section will include experts in risk assessment, oral and dermal toxicity of dioxin, carcinogenicity of dioxin, dose-response, exposure assessment, and probabilistic risk assessment. We generally identify 20-40 individuals, narrow the list to our top picks, and begin contacting these individuals to query them of their interest and availability. We review the CVs and credentials of those identified. Each promising candidate will then be evaluated for potential conflict of interest and bias issues. While panel members are selected for their scientific/technical expertise, they must be sufficiently independent. The evaluation of real or perceived bias or conflict of interest is an important consideration and every effort is made to avoid conflicts of interest and biases that would prevent a panel member from giving an independent opinion on the subject. *TERA*'s conflict of interest policy is found at http://www.tera.org/peer/COI.html.

TERA will be solely responsible for selection of the panel. We strive to include a range of perspectives on each panel, including diverse professional affiliations (e.g., industry, academic, government, and public interest) to balance perspectives. If the sponsor wishes, *TERA* can provide a short list of potential candidates to the sponsor to allow the sponsor to identify any conflict of interest issues that *TERA* may not be aware of with particular individuals. However,

to maintain the independence of the process, *TERA* must be solely responsible for selection of panel members. Scientific expertise is the first and most important criterion for panel selection.

Task 4: Meeting Arrangements

The peer review will be a 3-day meeting. The first day will be a peer review of the exposure assessment and will have a panel of appropriate expertise. The second and third day will be a peer review of the human health toxicity assessment and will have a panel of appropriate expertise. There will be 1 or more panelists that will serve on both panels to ensure review of all overlapping issues.

TERA will work with MDEQ or Dow to identify an appropriate meeting room to hold the meeting and make the meeting arrangements. *TERA* will coordinate travel and lodging for the panel.

If the sponsor decides that the meeting should be open to the public, *TERA* will share the review materials and logistical details of the meeting with the public via the meeting webpage, and pre-register all attendees. We use the Internet to share information on the meeting to the general public and those who may attend the meeting. All of the important information about this meeting will be included in a meeting web page (see for example, the web page for a peer review on.) The meeting page is updated frequently. Our goal is to provide all interested parties with the information they need to participate in the process.

TERA will develop the agenda for the meeting, which will include time for the sponsor or authors to briefly present information on the documents. We find it most helpful to have one or two of the authors sit at the table with the panel so that they can readily answer panel members' questions.

Approximately a month before the meeting, *TERA* will distribute the review package to the panel members. This includes the document, key references, the charge, agenda, and any additional information the panel needs. *TERA* can also post the document and list of key references on the meeting web page for easy access by observers and the public, if the sponsors wish. If key documents involve confidential business information, *TERA* will arrange for confidentiality agreements with the panel members and *TERA*.

Task 5: Meeting

TERA will provide two senior scientists for the meeting who will serve as the chair and co-chair, leading the panel discussion to address issues in the charge. Because this is a complex, long meeting, it is critical to provide staff with diverse scientific expertise that are knowledgeable about all aspects of the review. By having a chair and co-chair, they can share the duties of the meeting, providing backup to each other as needed to ensure that the meeting runs smoothly. The panel will strive for consensus, but if that is not possible areas of agreement and disagreement will be discussed and noted. To ensure an accurate record of key results of the meeting, the

Chair(s) will summarize the conclusions of the panel at key points during the meeting. If the meeting is open to the public, *TERA* can facilitate submission of technical comments prior to the meeting to share with the panel, and if desired, provide some limited amount of time on the agenda for brief comments at the meeting.

Task 6: Meeting Report

TERA will provide senior scientist(s) to take notes of all discussions and summarize these in a report. This report will not be a detailed transcript of the discussions; rather it will be a clearly articulated summary of the important discussion points and conclusions. This draft report will summarize the discussions of the panel and rationales for their conclusions and findings. The meeting report will clearly document when reviewers have divergent opinions. Our use of senior scientists who have reviewed the documents and understands the issues helps facilitate a high quality and timely report (rather than use of administrative staff or transcribers who may not grasp the content of the discussions). The panel and the chair will review a draft for accuracy, insuring the report reflects the discussions and conclusions of the meeting. The draft report will also be sent to the sponsor to ensure the accuracy of statements made by the sponsor and authors at the meeting. *TERA* will prepare the final peer review report, incorporating the comments from the sponsor, the panel and the Chair/Co-chair. The final report will be delivered to MDEQ and published by posting on the *TERA* review web page.

III. Staffing Requirements

Ms. Joan Strawson will serve as the overall project leader and technical point of contact for this effort. She has extensive experience in managing all aspects of complex peer consultation and peer review meetings. She has successfully conducted meetings on a variety of chemicals and diverse risk issues for both private and public sponsors. Reports from these meetings are found at www.tera.org/peer. Experienced *TERA* senior scientists will serve as the meeting Chair/Co-chair. Biographical sketches or CVs of the key personnel are available upon request.

IV. Program Duration and Deliverable

The schedule for the meeting will depend upon when the sponsor has the final document ready, when the panel members and sponsors are available for the meeting, and availability of meeting space. *TERA* will finalize the work plan and schedule after discussions with the sponsor. The following is a preliminary outline of the schedule.

Month 0

- *TERA* and sponsor discuss overall project, goals and approach. Decisions are made regarding public participation, meeting location, meeting format, etc
- *TERA* works with the sponsor to find an appropriate meeting facility.
- *TERA* reviews the draft report and provide comments on the document readiness to the sponsor by within 30 days of receiving report.
- *TERA* finalizes the work plan and schedule in consultation with the sponsor.

Month 1 – Timeline begins when the document is ready for the review

- *TERA* and sponsor discuss schedule and possible meeting dates.
- *TERA* develops charge questions and discusses with sponsor.
- *TERA* begins search for appropriate experts for both panels.

Month 2

- Short list of potential experts contacted and screened for conflict of interest and bias issues. Both panels selected.
- Date and location of meeting agreed upon with sponsor. *TERA* plans the meeting, makes logistical arrangements with facility.

Month 3

- *TERA* distributes review packages to panel

Month 4

- Panel members provide preliminary written comments and questions to the authors to allow them to better prepare for meeting.
- Meeting held in Midland, Michigan.

Four to Six Weeks Post Meeting

- *TERA* completes a draft meeting report and distributes to panel and sponsor for two week review period.

Four Weeks Post Receipt of Comments

- *TERA* finalizes meeting report and delivers to sponsor and panel; posts report on web.

V. Preliminary Estimate of Costs

This section contains a preliminary cost estimate for *TERA* labor and direct costs based on typical costs gleaned from our experience in conducting such peer reviews. We conduct peer consultations and reviews on a time and materials basis. While we can roughly estimate the costs, there are a number a variables that affect the costs, including number of panel members, fluctuation in travel costs, number of participants, the extent of the pre-review and subsequent discussions, and complexity of review materials and resulting meeting report, and the nature of any follow-up activities.

TERA will provide MDEQ with monthly invoices summarizing work accomplished and listing the hours worked for that month by person. Direct costs such as travel expenses, literature retrieval, courier services, conference calls, meeting rooms, refreshments, etc. will be invoiced at cost, without additional fee. Labor rates provided here are the projected 2008 fully loaded rates, reflecting a blend of government and industry rates. Payment is due 30 days after issue of invoice, with 1.5% interest accruing each month thereafter.

The following Cost Proposal is an estimate, based upon the following:

- The meeting will be a 3 day meeting.
- The meeting will be held in Midland, Michigan area at an appropriate facility.
- There will be two panels. The first panel will consist of 6-8 experts to address the exposure assessment/bioavailability issues and the second panel will consist of 8-10 experts to address the dioxin toxicity issues. One or more panelists will overlap.
- Meeting facility and refreshments not included in the cost proposal.

Our staffing plan with hourly labor rates are below:

Project Manager	$187
Sr. Scientist/Chair	$235
Sr. Scientist/Co-Chair	$185
Sr.Scientist/Notetaker	$194
Meeting Coordinator	$118
Admin. Assistance	$57

Estimated Level of Effort/Costs

Task Description	Labor Hours	Cost
Task 0: Project scoping and project management (schedule, etc)	70	12,470
Task 1: Chair and Project Manager review document to identify scientific issues and needed areas of expertise. TERA staff to notify MDEQ of any problems with document that could affect review	35	6,755
Task 2: Prepare charge and materials for review package. Distribute review package	65	8,510
Task 3: Select reviewers. Includes developing COI questionnaire, and disclosures, obtaining and forwarding CVs.	70	13,115
Task 4: Meeting Preparation and Logistics	215	30,040
Task 5: Hold Meeting	180	36,045
Task 6: Prepare meeting	175	32,170

report.		
Total Labor	**810**	**139,105**
Direct Expenses: Honorarium: $1000 per person per day Copies, Mailing etc Travel (4 TERA staff and 16 panel members)		 28,000 1,374 28,710
Total Direct Expenses		**58,084**
Grand Total		**197,189**

MDEQ will hold *TERA* harmless for any and all loss, damages, costs, legal fees, and expenses on account of any and all claims or actions brought against the Sponsor by any person, firm, corporation, or other entity as a result of or otherwise arising out of the advice, analysis, review or testimony rendered by *TERA*, its personnel, or peer experts, for or on behalf of specific projects for MDEQ.

_____ Date:

Michael Dourson
President
For: Toxicology Excellence for Risk Assessment